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Dated: December 22, 2008 Signature: /Marshall P. Byrd/ #62,454
(Marshall P. Byrd)

Docket No.: 29853/37704A
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Joseph Senesac

Application No.: 10/649,974

Confirmation No.: 7068

Filed: August 27, 2003

Art Unit: 1651

For: CHROMATOGRAPHIC METHODS FOR
ADENOVIRUS PURIFICATION

Examiner: L. B. Lankford

SUBMISSION FOR PRE-APPEAL BRIEF CONFERENCE

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants request review of the claim rejections contained in a final Office Action mailed August 21, 2008 in the above-identified matter. Each of the claims under examination, *i.e.*, claims 1-69, has been rejected twice and is now finally rejected (claims 70-73 were previously withdrawn). Therefore, claims 1-69 are in condition for the requested review. No amendments are being filed with this request. This paper is filed concurrently with a Notice of Appeal and fee, and includes no more than five pages of patentability argument. Reconsideration is respectfully requested in view of the following remarks.

Remarks begin on page 2.

REMARKS

I. The nature of the invention

The instant application concerns methods for purifying adenovirus particles which provide an efficient protocol to generate substantially purified adenovirus. Specifically, claimed purification methods comprise at least two chromatography steps wherein at least one chromatography step involves the binding of an adenovirus to the chromatographic medium and at least one chromatography step wherein the chromatographic medium, which is not solely a size exclusion medium, retains one or more contaminants in the adenovirus preparation.

II. Pending rejection

The Final Office Action of August 21, 2008, maintained the only rejection pending in the Application and asserted that claims 1-69 are obvious, under 35 U.S.C. §103(a), over a single cited reference (Huyghe et al. Hum. Gen. Ther., 6:1403-1416, 1995). The rejection of record, however, lacks the support required to establish a *prima facie* basis for obviousness of any of the claims. Absent any *prima facie* rejection on the record, Applicants request that all rejections be withdrawn.

Huyghe et al. fails to teach or suggest all claimed steps

In the instant rejection, the Examiner cites Huyghe et al. and states that Huyghe et al. “teaches a variety of different chromatographic methods for purifying adenovirus.” The rejection, however, fails to identify where Huyghe et al. teaches **any of the elements** of any of the pending claims, much less how Huyghe et al. teaches or suggests **all elements** of all rejected claims as required to reach a conclusion of *prima facie* obviousness. In particular, Huyghe et al. fails to teach or suggest a chromatographic step with a medium that retains one or more contaminants from a virus elute wherein the medium is not solely a size-exclusion medium. In view of this shortcoming Applicants assert that no *prima facie* rejection has been made and the Examiner has failed to shift the burden to the Applicants.

Huyghe et al. teaches away from the claimed method

Each chromatography medium that was tested in Huyghe et al. retains adenovirus particles and allows contaminants to pass through the medium (virus particles are then eluted from the medium). The only *attempt* by Huyghe et al. to employ a medium to retain

contaminants while allowing adenovirus particles to pass there-through is the use of a size-exclusion medium. However, as detailed in Huyghe et al., use of size-exclusion medium proved ineffective in providing purified adenovirus particles and the medium actually retained the majority of the viral particles¹. Thus, beyond the failure of Huyghe et al. to teach or suggest a purification step which employs a medium to retain contaminants and which is not solely a size-exclusion medium, Huyghe et al. teaches that even a chromatographic medium designed to retain contaminants (*i.e.*, a size exclusion medium) failed to affect virus purification. The teachings of Huyghe et al. would have indicated to the skilled worker that chromatographic medium designed to retain contaminants and allow virus to pass there-through should not be employed in adenovirus purification methods. Hence, the disclosure of Huyghe et al. teaches away from the methods recited in the instant claims.

Huyghe et al. fails to teach or suggest features of dependent claims

Finally, the instant rejection has been improperly applied to all of the pending claims in the case. As outlined above, in order to form a *prima facie* case for obviousness the Examiner must identify how cited reference(s) teach or suggest all elements of the claims. However, the grounds for the rejection fail to identify how Huyghe et al. teaches any of the elements of the instant claims much less all elements of all claims. For instance, no teaching or suggestion concerning the use of dye affinity medium in the purification of adenovirus (*see, e.g.*, claims 6-8, 20-22 and 30-32) has been identified in Huyghe et al. and there is no teaching as to whether a dye affinity medium would retain virus particles or would retain contaminants. Likewise, no teaching or suggestion has been identified in Huyghe et al. or any other reference regarding the use of heparin affinity media for use in chromatographic purification of adenovirus (*see, e.g.*, claims 34 and 35). Thus, even if a *prima facie* rejection of some claims was articulated by the Examiner, no *prima facie* rejection of all claims has been set forth on the record.

¹ In particular, Huyghe et al. noted that the eluting fraction comprised a very broad UV absorbance peak (indicating poor separation of contaminants) and Huyghe et al. indicated that the method resulted in a “very low” yield, *i.e.*, most of the virus remained on the column (*see*, page 1408, paragraph 3 of Huyghe et al.).

For the foregoing reasons, Applicants submit that the rejection of claims 1-69 as obvious, under 35 U.S.C. §103(a), over Huyghe et al. has been overcome and the rejection should be withdrawn.

Dated: December 22, 2008

Respectfully submitted,

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) <div style="text-align: center;">29853/37704A</div>	
	Application Number <div style="text-align: center;">10/649,974-Conf. #7068</div>	Filed <div style="text-align: center;">August 27, 2003</div>	
	First Named Inventor <div style="text-align: center;">Joseph Senesac</div>		
	Art Unit <div style="text-align: center;">1651</div>	Examiner <div style="text-align: center;">L. B. Lankford</div>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>62,454</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> </div> <div style="width: 35%; text-align: center;"> <p>_____ /Marshall P. Byrd/ #62,454 Signature</p> <p>_____ Marshall P. Byrd Typed or printed name</p> <p>_____ (312) 474-6300 Telephone number</p> <p>_____ December 22, 2008 Date</p> </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<input type="checkbox"/> *Total of <u>1</u> forms are submitted.			

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